

EU DECLARATION OF CONFORMITY

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Manufacturer: Orantech Inc.

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SRN : CN-MF-000013859

EC- Representative: Cables and Sensors B.V.

Zekeringstraat 21B , 1014 BM Amsterdam, Netherlands

SRN : NL-AR-000012545

Product Name : TOCO Fetal transducer

Product Models : Please see the Annex I

Basic UDI - DI: 69416919ORANTECH11QS

UMDNS Code : 14119

Classification : Class IIa , Rule10 (Annex VIII of MDR 2017/745/EEC)

Conformity Assessment Route : According to Annex IX chapter I and III of MDR 2017/745/EEC

We, Orantech Inc., herewith declare that this EU declaration of conformity is issued under the sole responsibility of the manufacturer. The products mentioned above are in conformity with the Medical Device Regulation, the provisions of council MDR 2017/745/EEC of 26 May, 2020 concerning medical devices. All supporting documentations are retained under the premises of the manufacturer. We, the manufacturer, are exclusively responsible for doc.

Standard Applied :

EN ISO 14971:2019	IEC60601-2-37:2007+AMD1:2015
IEC 60601-1:2005/A1:2012	IEC 60601-1-2:2014
EN ISO 15223-1:2020	EN 1041:2008
IEC62366 : 2015	EN ISO 10993-1:2018
EN ISO 10993-5:2009	EN ISO 10993-10:2010

Notified Body : TÜV SÜD Product service GmbH Ridlerstr 65, D-80339 München, Germany

CE mark: 

EC Certificate No. : G1 098084 0003 Rev. 01

Valid Date From : 2020-07-10

Valid Date Until : 2024-07-10

Place, Date of Issue :

Shenzhen, July. 1st, 2021

Signature : 

Position: General Manager

Annex I List of TOCO Fetal transducer

Model	UDI-DI	Model	UDI-DI
FTC-PH01	6970706360545	FTC-SC02	6970706360606
FTC-GE01	6970706360552	FTC-SL01	6970706360613
FTC-GE02	6970706360569	FTC-SL02	6970706360620
FTC-AL01	6970706360576	FTC-SL03	6970706360637
FTC-SC01	6970706360583	FTC-NT01	6941691955528
FTC-ED01	6970706360590	FTC-BN01	6941691955535